REMARKS

In the Non-final Office Action mailed June 11, 2008, claims 1, 4, 11-38, 59-62, 81-82, 87 and 89-93 were pending and stood rejected. Further consideration of the present application including claims 1, 4, 11-38, 59-62, 81-82, 87 and 89-93 is respectfully requested.

Claims 36-38 stand rejected under 35 USC §102(b) as anticipated by U.S. Patent No. 5,423,826 to Coates et al. In maintaining the rejection based on Coates, the examiner asserts that Fig. 19 in Coates discloses guide member 180 mounted to the stationary member and spaced proximally from the plate. Coates et al. discloses that Fig. 19 "is an exploded view of a guide assembly...." See col. 5, line 31. As one of ordinary skill in the art would understand, guide member 180 is shown in an exploded view from its assembled configuration with foot 157, as indicated by the line connecting the distal end of guide member 180 to foot 157. This is further explained in the specification at col. 13, lines 33-38, where it discloses guide member "is placed in the unused hole in each end of the guide 150.... The sleeve 180 is then removed and a bone screw 30 is placed through the same hole in the foot 157 of the guide 150." See also col. 14, lines 7-17. Coates et al. disclose that guide member 180 is mounted in foot 157, but there is no disclosure that guide member 180 is mounted to any portion of either of members 151, 152 of instrument 150 proximally of foot 157. Therefore, claim 36 is not disclosed in Coates et al. and withdrawal of the rejection of claim 36 along with claims 37-38 depending therefrom is respectfully requested.

Claims 1, 4, 11-14, 18, 20-27, 81-82, 87, 92 and 93 stand rejected under 35 USC §103(a) as being unpatentable in view of U.S. Patent App. Pub. No. 2003/0105462 to Haider alone. Claim 1 recites, among other features, "wherein said first and second members each include a maximum width transversely to said longitudinal axis from said inner side surface to said outer side surface thereof that is uniform along a length of said visualization opening, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined."

The examiner has not identified any teaching or suggestion of these features of claim 1 in Haider or in any other prior art reference. For example, the members along the central element in Haider do not include a uniform maximum width along the central element. Rather, the

members have a variable width due the different curvatures of the inner and outer side surfaces of the walls along the central element. Furthermore, there is no disclosure or teaching that the minimum width of the central element is greater than the combined maximum widths of the members along the central element. Identification of any disclosure or teaching of these elements in Fig. 2 and paragraphs [0027]-[0034] of Haider would be appreciated so the same may be considered and rebutted. Also, the examiner does not provide any reasoning as to why one of ordinary skill in art would modify Haider to arrive at the claimed invention. An obviousness rejection can not be supported by mere conclusory statements. KSR International Co. v. Teleflex Inc., 550 U.S. ___, 82 USPQ2d 1385, 127 S.Ct 1727, 167 L.Ed.2d 705 (U.S. 2007), citing In Re Kahn, 441 F.3d 977, 988 (CA Fed. 2006), stated: [R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

The examiner relies on In re Aller to support the rejection and states "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the a visualization opening with the claimed length-to-width ratios, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." A review of claim 1 does not reveal any claimed length-to-width ratios, so the relevance of the examiner's application of In re Aller to claim 1 is not clear. In any event, In re Aller actually provides that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." MPEP §2131.03 goes on to note that prior art which teaches a range within, overlapping, or touching the claimed range anticipates if the prior art range discloses the claimed range with "sufficient specificity." See MPEP 2131.03

Moreover, in related MPEP §2144.05 concerning obviousness of ranges, the PTO notes that overlap of ranges establishes a *prima facie* case of obviousness. The MPEP states:

> In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) . . . .

> "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). However, if the reference's disclosed range is so broad as to encompass a very large number of possible distinct compositions, this might present a situation analogous to the obviousness of a species when the prior art broadly discloses a genus. *Id.* See also *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); *In re Jones* , 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); MPEP § 2144.08. . . .

Haider is completely silent as to any minimum width of the central element in comparison to the combined maximum widths of members extending along the central element. Therefore, there is no specificity with which Haider can be properly considered to disclose these features, and it is not possible to determine how the minimum width of the central element in Haider compares to the combined maximum widths of members extending along the central element or why one of ordinary skill in the art would modify Haider to arrive at the claimed invention. Therefore, for at least these additional reasons, a prima facie case for rejecting claim 1 has not been established, and withdrawal of this basis of the rejection of claim 1 is respectfully requested along with claims 4, 11-14, and 18 depending from claim 1.

Claim 20 recites, among other features, "wherein said intermediate portion includes a first member along one side of said visualization opening and a second member along the opposite side of said visualization opening, said first and second members each including an outer side surface defining an outer most side of said plate and an inner side surface opposite said outer side surface, said inner side surfaces defining respective opposite sides of said visualization opening that extend along said longitudinal axis, wherein said first and second members each include a maximum width transversely to said longitudinal axis between said inner side and said outer side surface thereof, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined." As discussed above with respect to claim 1, Haider fails to disclose or suggest at least these features in claim 20, and the Office Action does not establish a prima facie case for rejecting claim 20 based on Haider. Therefore, withdrawal of this basis of the rejection of claim 20 is respectfully requested along with claims 21-22 and 92-93 depending from claim 20.

Claim 81 recites, among other features, "wherein said intermediate portion includes a first member along one side of said visualization opening and a second member along an opposite side of said visualization opening, said first and second members each include a concavely curved outer surface extending along opposite outer edges of said plate between said first and second connection portions, said first and second members further including a convexly curved inner surface opposite said outer surface thereof, said inner surfaces extending along and defining respective sides of said visualization opening, wherein said inner and outer surfaces of said first member and said inner and outer surfaces of said second member each define a width along said longitudinal axis that is uniform along a length of said visualization opening." Haider also fails to disclose or suggest at least these features in claim 81. For example, the members along the central element in Haider do not include a uniform width along the central element. Rather, the members have a variable width due the different curvatures of the inner and outer sides of the walls along the central element. The Office Action does not provide any reference that teaches these features of claim 81 nor does it provide any reasoning why one of ordinary skill in the art would modify Haider to arrive at claim 81.

As discussed above with respect to claim 1, Haider also does not disclose or teach that the minimum width of the central element is greater than the combined maximum widths of the members along the central element, and therefore Haider does not teach claim 87. Withdrawal of this basis of the rejection of claims 82 and87 depending from claim 81 is respectfully requested.

Claims 1, 4, 11-15, 18-27, 81-82, 87, 92 and 93 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,413,259 to Lyons et al. alone. The examiner recognizes that Lyons et al. fails to disclose and hour-glass shape of the visualization opening, the curvatures of the sidewalls of the visualization opening, and the widths and the length-to-width ratios of the visualization opening. Despite these deficiencies, the examiner asserts that it would have been obvious matter of design choice to one skilled in the art at the time the invention was made to have provided the visualization opening with the claimed shapes of the walls, since "applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a visualization opening" In re Dailey and Eilers, 149 USPQ 47 (1966).

As an initial matter, the assertion that applicant has not disclosed the claimed visualization opening solves any stated problem or is anything more than one of numerous shapes of configurations that could be employed is factually incorrect. The specification in the present application includes disclosure of the advantages provided and problems solved by the shape of the visualization opening, the walls around the visualization opening, and the members along the sides of the visualization opening. Examples of such disclosure can be found, for example, at lines 7-17 of paragraph 57, paragraph 58, and lines 1-11 of paragraph 59, paragraph 77, paragraphs 79-80, and paragraph 89 of the publication of the present application. In summary, the claimed features provide optimum visualization capabilities, a reduced lateral profile of the plate along the intermediate portion of the plate and visualization openings, while also providing the plate with sufficient load bearing strength and minimizing stress concentrations. Accordingly, the examiner's assertion is traversed.

The examiner states in the Response to Arguments section of the Office Action that "Applicants' disclosure as originally filed states that the visualization openings 60 can take other shapes and sizes (page 12, lines 22-23). It is the examiner's position that the claimed features are rendered obvious when a person of ordinary skill in the art changes the size and/or shape of visualization opening 28." It is respectfully submitted that Applicant is not claiming the other shapes and sizes, but rather is claiming the features of the visualization opening that provide the advantages discussed above. Furthermore, applicants' specification actually states "it should be understood that other embodiments contemplate other sizes and shapes for the visualization openings 60." Applicant is not claiming these other embodiments, and Applicants' disclosure that other shapes and sizes are possible for other embodiments is not a teaching upon which the examiner may properly rely in modifying a reference since Applicants' disclosure is not a prior art reference.

It is not apparent, nor has the examiner explained, why the disclosure of a circular aperture 28 in Lyons et al. would have suggested the claimed visualization opening with the curvatures and widths of the sidewalls of the visualization opening and the members along the sides of the visualization opening. The examiner attempts to overcome these deficiencies in the prior art by citing In re Dailey, 149 USPQ 47 (CCPA 1966) for the proposition that no patentable moment is derived from the claimed features. The application of Dailey is not legally sound in the present

circumstance. In Dailey, the court stated that "[a]ppellants have presented no argument which convinces us that the particular configuration of their container is significant or is anything more than one of numerous configurations a person of ordinary skill in the art would find obvious." In re Dailey, 149 USPQ at 50. In contrast, applicants' specification (see for example, at lines 7-17 of paragraph 57, paragraph 58, and lines 1-11 of paragraph 59, paragraph 77, paragraphs 79-80, and paragraph 89) establishes that the shape of the visualization opening, the walls around the visualization opening, and the members along the sides of the visualization opening solve, among other problems, problems associated with optimizing visualization capabilities while providing the plate with sufficient load bearing strength and minimizing stress concentrations. The circular opening in Lyons et al. fails to address these problems in the manner claimed, and the claimed features are significant in that they solve a stated problem. Accordingly, it is respectfully submitted that the claimed features cannot be properly dismissed as an obvious matter of design choice.

Claim 1 recites, among other features, "wherein said first and second members each include a maximum width transversely to said longitudinal axis from said inner side surface to said outer side surface thereof that is uniform along a length of said visualization opening, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined." The examiner has not identified any teaching or suggestion of these features of claim 1 in Lyons et al. or in any other prior art reference. For example, the members along circular hole 28 in Lyons et al. do not include a uniform maximum width along the circular hole. Rather, the members have a variable width due the concave curvature of the inner surface around hole 28 and the linear profile of the outer surface of the plate along hole 28. Furthermore, there is no disclosure or teaching that the minimum width of hole 28 is greater than the combined maximum widths of the members along hole 28. The examiner does not provide any reasoning as to why one of ordinary skill in art would modify Lyons et al. to arrive at the claimed invention. As discussed above, an obviousness rejection can not be supported by mere conclusory statements, and rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational

underpinning to support the legal conclusion of obviousness. Therefore, withdrawal of the rejection of claim 1 is respectfully requested along with claims 4, 11-15, and 18-19 depending therefrom.

Lyons et al. also fail to disclose or suggest the features in claim 20. For example, as discussed above with respect to claim 1, there is no disclosure or teaching in Lyons et al. or any other cited reference that the minimum width of hole 28 is greater than the combined maximum widths of the members that extend along hole 28. As also established above, these features in claim 20 are significant and not merely a matter of design choice. Therefore, withdrawal of this basis of the rejection of claim 20 is respectfully requested along with claims 21-27 and 92-93 depending from claim 20.

Lyons et al. also fail to disclose or suggest the features in claim 81. For example, the members along hole 28 in Lyons et al. do not include a uniform width along hole 28. The members have a variable width due the different curvatures of the inner and outer surfaces of the members along hole 28. Therefore, withdrawal of the rejection of claim 81 based on Lyons et al. is respectfully requested. Also, as discussed above, Lyons et al. also do not disclose or teach that the minimum width of hole 28 is greater than the combined maximum widths of the members along the hole 28 and therefore do not teach claim 87. Withdrawal of this basis of the rejection of claim 87 along with claim 82 depending from claim 81 is respectfully requested.

Claims 16-17, 28-35 and 89-91 stand rejected as being unpatentable over Lyons et al. in view of U.S. Patent No. 6,193,721 to Michelson. Claims 16 and 17 depend from claim 1 and are allowable at least for the reasons claim 1 is allowable over Lyons et al. as discussed above.

Claim 28 recites, among other features, a plate and a holding instrument that includes a holding system engaged to the plate by clamping end walls of the plate, and "wherein said first and second holding members move toward and away from one another in a direction that follows said longitudinal axis of said plate and further comprising a pair of guide members on said holding instrument positioned on opposite sides of said longitudinal axis when said holding system is engaged to said plate." The examiner does not provide any indication of how or where the cited references are considered to disclose or teach this combination of features of the holding instrument. The Office Action does not identify any disclosure or teaching of the claimed pair of guide members positioned on opposite sides of the longitudinal axis of the plate when the holding instrument is

engaged to the plate in a direction that follows the longitudinal axis of the plate as recited in claim 28. Therefore, a prima facie case for rejecting claim 28 has not been established and withdrawal of the rejection of claim 28 is respectfully requested.

Claims 29-35 depend from claim 28 and are also allowable at least for the reasons claim 28 is. Furthermore, at least claims 32 and 34 recite features that also not disclosed or suggested in the cited references. For example, claim 32 recites "wherein said connecting system includes a stationary member and a linkage movable relative to said stationary member with said handle system to move said first holding member relative to said second holding member to engage said plate therebetween, said pair of guide members being mounted to said stationary member proximally of said holding system." The examiner has not identified how or where the references disclose or teach these features including a pair of guide member mounted to the stationary member proximally of the holding system. Claim 34 recites "wherein said second holding member is fixed and said first holding member is pivotally attached to said second holding member and movable relative to said second holding member and said pair of guide members between a clamping position and a release position while said second holding member and said pair of guide members are stationary." The examiner has not indicated how or where the cited references teach or disclose this arrangement between the holding members or the arrangement of the pair of guide members relative to the holding members. A prima facie case for rejecting at least claims 32 and 34 depending from claim 28 has not been established in the Office Action. Therefore, withdrawal of the rejection of claims 29-35 depending from claim 28 is also requested.

With respect to claim 89, the examiner has not identified any portion of the cited references that teach or suggest a plate and holding instrument combination where the holding instrument also includes at least one guide member mounted to a stationary member of an actuating system with the guide member positioned relative to the longitudinal axis of the plate "in offset relation to said longitudinal axis so that said at least one guide member is positioned relative to said plate to guide placement of a bone engaging fastener through said at least one hole when said first and second holding members are engaged to said plate along said longitudinal axis." The examiner identifies elements 54 in Michelson as guide members, but elements 54 are not arranged in the manner recited

for the at least one guide member of claim 89. Therefore, withdrawal of the rejection of claim 89 is respectfully requested along with claims 90 and 91 depending therefrom.

Claims 1, 4, 11-15, 18, 20-27, 92 and 93 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,954,722 to Bono et al. alone. The examiner admits that, like Lyons et al. discussed above, Bono et al. fail to disclose a visualization opening having an hourglass shape, concave/convex curvatures of the visualization opening walls, and the claimed widths and the length-to-width ratios. The examiner does not cite any prior art reference that teaches these features, and appears to rely on In re Dailey and Eilers to assert that the features recited in these claims are an obvious matter of design choice.

As discussed above with respect to Lyons et al., the specification in the present application includes disclosure of the advantages provided and problems solved by the claimed visualization opening, the walls around the visualization opening, and the members along the sides of the visualization opening. The examiner refers to a visualization opening 59 in Bono et al., but there does not appear to be any element 59 disclosed in Bono et al. Clarification of the same is respectfully requested is this is incorrect. With respect to graft holes 25, it is not apparent, nor has the examiner explained, why the disclosure of graft holes 25 in Bono et al. would have suggested the claimed shape, curvature and widths for the visualization opening and adjacent members in claim 1. The examiner attempts to overcome these deficiencies in the prior art by citing In re Dailey. However, graft holes 25 in Bono et al. fail to address the problems solved by the present invention in the manner claimed in the present application. Since, as discussed above with respect to Lyons et al., the claimed features are disclosed as significant, it is respectfully submitted that the claimed features cannot be properly dismissed as an obvious matter of design choice.

Claim 1 recites, among other features, "wherein said first and second members each include a maximum width transversely to said longitudinal axis from said inner side surface to said outer side surface thereof that is uniform along a length of said visualization opening, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined." The examiner has not identified any teaching or suggestion of these features of claim 1 in Bono et al. or in any other prior art reference. For

example, the members along graft hole 25 in Bono et al. do not include a uniform maximum width between the linear inner surface along graft hole 25 and the concavely curved outer surface along the plate. Rather, the members have a variable width. Furthermore, there is no disclosure or teaching that the minimum width of graft hole 25 is greater than the combined maximum widths of the members along graft hole 25. The examiner does not provide any reasoning as to why one of ordinary skill in art would modify Bono et al. to arrive at the claimed invention. As discussed above, an obviousness rejection can not be supported by mere conclusory statements, and rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. Therefore, withdrawal of the rejection of claim 1 is respectfully requested along with claims 4, 11-15, and 18 depending therefrom.

Bono et al. also fail to disclose or suggest the features in claim 20. For example, as discussed above with respect to claim 1, there is no disclosure or teaching that the minimum width of graft hole 25 is greater than the combined maximum width of the members that extend along graft hole 25. Therefore, withdrawal of this basis of the rejection of claim 20 is respectfully requested along with claims 21-27 and 92-93 depending from claim 20.

Claims 59-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bono et al. in view of Boucher et al. and, separately, over Lyons et al. in view of Boucher et al. Claim 59 recites, among other features, "wherein said first and second members each include a maximum width transversely to said longitudinal axis between said inner side and said outer side surface thereof, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined."

With respect to claim 59, as discussed above, it is respectfully submitted that Bono et al. and Lyons et al. fail to disclose or suggest that the minimum width of either graft hole 25 or circular hole 28 thereof, respectively, is greater than the combined maximum width of the members that extend along graft hole 25 or hole 28 in the manner recited in claim 59. The examiner has cited no prior art reference or public document that teaches this arrangement, but rather appears to rely on applicant's disclosure to teach these features, but applicant's disclosure is not a reference upon which the

examiner may properly rely to support a rejection. Boucher et al. fail to remedy these deficiencies in Bono et al and Lyons et al. Therefore, claim 59 is allowable.

In responding to applicants' previous arguments, the examiner states "Bono clearly discloses a visualization opening 59. It is the Examiner's position that the claimed features are rendered obvious when a person of ordinary skill in the art changes the size and/or shape of the opening." A review of Bono et al. did not reveal any opening or any other element labeled with reference numeral 59. The examiner has not identified any teaching or suggestion of the claimed features in the prior art, or provided any reference that teaches modifying Bono to arrive at the claimed invention of claim 59. The examiner asserts that the invention is rendered obvious when one of ordinary skill in the art changes the size and/or shape of the visualization opening of Bono et al., but the examiner has not provided any reason why one of ordinary skill in the art would modify Bono et al. to arrive at the claimed invention when there appear to be an unlimited number of ways the size and/or shape of the opening of Bono et al. could be changed. It is respectfully submitted that the examiner's statement that the "claimed features are rendered obvious when a person of ordinary skill in the art changes the size and/or shape of the opening" and similar statements made in rejecting claims 1, 20, is not a proper reference[1] -- being neither a public document that can be authenticated (such as a patent or other publication) nor an affidavit/declaration of personal knowledge per MPEP §2144.03. If the examiner's knowledge or the asserted teaching is derived from applicant's disclosure, then the rejection is not proper since applicant's specification is not a reference upon which the examiner may properly rely to support a rejection.

The references also fail to teach or suggest the uniform width of the members between the inner and outer side surfaces along the visualization opening as recited in claim 60. The examiner asserts that Bono discloses a uniform width along the visualization opening to the extent Applicant does and compares Fig. 2 of Bono et al. with Applicants "uniform width" as shown in Fig. 3 of Applicants disclosure. The width of the elements along the holes 25 in Bono et al. are defined between a linear inner wall surface and a concavely curved outer wall surface that extend along the opening, and since the spacing between a line and a curve is variable along the entire length of the line and curve Bono et al. completely lacks any uniform width along holes 23. In contrast, Fig. 3 in applicant's disclosure includes a width between a concavely curved outer surface and a convexly

curved inner surface arranged where the convexity of the curves are oriented in the same direction, providing a uniform spacing of the curved surfaces. These differences between Fig. 2 of Bono and applicant's Fig. 3 are substantial and would be readily apparent to one of ordinary skill in the art. Lyons et al. suffers a similar deficiency in that the inner wall surface along the hole is concavely curved and the outer surface along the plate is linear. Therefore, withdrawal of this basis of the rejection of claim 60 along with claims 61-62 depending from claim 59 is respectfully requested.

In view of the foregoing, the present application including claims 1, 4, 11-38, 59-62, 81-82, 87 and 89-93 is in condition for allowance. The examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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